Application/Control Number: 10/563,189 Page 2

Art Unit: 1638

DETAILED ACTION

1. Applicant's election of Group III (claims 16-20) in the reply filed on 30 June 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-15 are withdrawn from consideration as being drawn to nonelected inventions.

- 2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.
- 3. The drawings filed 30 December 2005 are objected to because the lettering is blurry in all figures, none of the lettering can be made out in the shaded boxes in Fig 1a-b, 2, and 7, and nothing can be made out in Fig 4-5. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

Claim Objections

4. Claim 19 is objected to for its recitation "human HSA" as this repeats "human" twice, effectively saying "human human serum albumin".

Application/Control Number: 10/563,189 Page 3

Art Unit: 1638

5. Claim 17 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. Claim 17 merely recites an inherent property of inclusion bodies

without reciting anything different about the HSA in claim 17 from that in claim 16.

6. Claims 18-20 are objected to under 37 CFR 1.75(c), as being of improper dependent form

for failing to further limit the subject matter of a previous claim. Applicant is required to cancel

the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. Parent claims 16-17 require that the HSA be present in inclusion

bodies. Thus, claims 18-20, in which the HSA is not in the inclusion bodies, is broader than the

parent claims.

7. Claims 19-20 are objected to under 37 CFR 1.75(c), as being of improper dependent form

for failing to further limit the subject matter of a previous claim. Applicant is required to cancel

the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. Claims 19-20 merely recite an inherent property of the HSA

without reciting anything different about the HSA in claims 19-20 from that in claim 18.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the

subject matter which the applicant regards as his invention.

Application/Control Number: 10/563,189 Page 4

Art Unit: 1638

9. Claims 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 16 is indefinite for being dependent upon a nonelected claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 11. Claims 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniell (WO 01/72959) taken with the evidence of the instant specification.

Daniell discloses human serum albumin (HSA) produced by transforming plastids with a vector comprising the psbA 5'UTR, a sequence encoding HSA and flanking sequences, and isolating the HSA (pg 88-90, 262-276, Fig 1 on pg 277, Fig 2-4 on Fig pg 18; Fig 9 on Fig pg 20). Inclusion bodies containing the HSA would inherently be formed, as disclosed in the instant specification, pg 29, lines 5-14, and pg 34, line 15, to pg 35, line 31).

12. Claims 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wichman et al (1974, Biochim. Biophys. Acta 372:218-224).

Wichman et al disclose human serum albumin (HSA) (Table 1, pg 223, paragraphs 4-6). Because this is native HSA, it is structurally equivalent to itself.

Application/Control Number: 10/563,189 Page 5

Art Unit: 1638

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

October 24, 2008

/Anne R. Kubelik/ Primary Examiner, Art Unit 1638